

## REMARKS

Applicants would like to thank Examiner Williams for her time and for her helpful suggestions during a telephone interview on May 18, 2005 with inventor Aaron Barnes.

Claims 1 – 19, 21 – 35, and 39 – 57 are pending in the application. Applicants gratefully acknowledge the allowance of claims 39 – 57. Claims 1 – 19, and 21 – 35 have been rejected. Claims 1 – 3, 5, 25, 39, 44, 46, and 49 have been amended. The amendments to the claims are supported by the specification as filed, and no new matter is presented. Claim 7 has been canceled without prejudice. Favorable reconsideration in light of the following remarks is respectfully requested.

### *Claims 1 – 7, 12, 14 – 19, and 25 – 33 Are Novel Over DeCamp et al*

Claims 1 – 7, 12, 14 – 19, and 25 – 33 have been rejected under 35 U.S.C. §102(b) as being unpatentable over DeCamp et al (US Pat# 5,792,099). Applicants respectfully traverse the rejection.

DeCamp describes a cannula for the delivery of viscoelastic material to the anterior chamber of the eye. DeCamp neither teaches nor suggests a microcatheter system, “wherein the flexible cannula is configured to be inserted into a retinal vein or artery and to remain in the retinal vein or artery during infusion and has an outer diameter less than about 100  $\mu$ m and the second cannula is configured to be inserted into the eye.” See column 4, lines 23 – 31 of Decamp, wherein DeCamp teaches that the larger diameter portion 36 is **connected to an end** of the second section 40. Thus, the second section is not mounted in the larger diameter portion. DeCamp device is design to inject viscoelastic with a viscosity of 5,000 – 60,000 cp which is very unlikely too be able to pass at any velocity through the claimed cannula. In addition, the lengths of cannulas identified by DeCamp would not be capable of reaching retinal arterys in the back of the eye when inserted through standard of care pars plana incisions As DeCamp does not teach each and every claim element and could not, in fact, function for the intended purpose of the claimed device, the present claims are novel over DeCamp. Accordingly, applicants request the withdrawal of the rejection and allowance of the claims.

***Claims 1 – 7, 12, 14 – 16, 19, 21, and 23 – 33 Are Novel Over Grinblat et al***

Claims 1 – 7, 12, 14 – 16, 19, 21, and 23 – 33 have been rejected under 35 U.S.C. §102(b) as being unpatentable over Grinblat et al (US Pat# 5,545,153). Applicants respectfully traverse the rejection.

Grinblat describes an illuminated infusion cannula for vitreoretinal procedures. Infusions cannulas are relatively short and are used to maintain the intraocular pressure within the eye during a surgical procedure. Grinblat et al neither teach nor suggest a microcatheter system “wherein the flexible cannula is configured to be inserted into a retinal vein or artery and to remain in the retinal vein during infusion and has an outer diameter less than about 100  $\mu\text{m}$  and the second cannula is configured to be inserted into the eye.” See Col. 4, lines 14 – 31, wherein Grinblat et al teach that tube 26 is preferable 20mm OD and that plate 28 is configured to be removably sewn to the eyeball at the start of the operation. This suturing plate on the infusion cannula (28) actually prevents the infusion cannula from extending too far into the eye, certainly not enough to reach the retina (it is only 4.00mm long). From this teaching, one of skill in the art would understand that tube 26 was to remain on the outside of the eyeball and is not configured to be inserted into the retinal vein because it is **too large** and would be prevented from doing so by the plate member 28. In contract to Griblat’s 20 mm tube, the claimed flexible cannula has an outer diameter less than about 100  $\mu\text{m}$ . Thus, Grinblat does not teach each and every claim element, the present claims are novel over Grinblat. Accordingly, Applicants request the withdrawal of the rejection and allowance of the claims.

***Claims 1 – 4, 12 – 16, 19, 21 – 23 and 25 – 33 Are Novel Over Le et al***

Claims 1 – 4, 12 – 16, 19, 21 – 23 and 25 – 33 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Le et al (US Pat#6,355,027) in view of applicant's own disclosure. Applicants respectfully traverse the rejection.

The claims as amended require, “wherein the flexible cannula is configured to be inserted into a retinal vein and to remain in the retinal vein during infusion and has an outer diameter less than about 100  $\mu\text{m}$  and the second cannula is configured to be inserted into the eye.” Nowhere does Le disclose, teach or suggest a “wherein the flexible cannula is configured to be inserted into a retinal vein and to remain in the retinal vein during infusion and has an outer diameter less than about 100  $\mu\text{m}$  and the second cannula is configured to be inserted into the eye.” For

example, see Col. 2, lines 51 – 58, wherein Le teaches that catheter tube 16 can range from 100 to 160 cm in length. Thus, the strain relief 14, which is not a second cannula according to the instant claims, is not configured to be inserted into a retinal vein and to remain in the retinal vein during infusion. In fact, Le's second cannula (14) is not even inserted into the eye and is clearly described as a strain relief. That is, Le's strain relief prevents Le's device from operating in this fashion. The device of Le is not capable of performing the claimed function of the instant device as suggested by the Examiner. Le also differs from the claimed device in that Le's flexible cannula (16) extends through (14) for the full length and the inner lumen of 14 doesn't contact any fluid Le describes "one-piece" tube (16). Importantly, Le's device has multiple layers and steel braid, which render it too stiff and thus incapable of functioning in the claimed methods. In fact, the atraumatic tip (18) of Le's device is designed not to puncture a vein or artery and would not be able to puncture retinal arteries.

As Le does not disclose, teach or suggest each claim limitation, and it is impermissible for the Examiner to cite Applicants' own disclosure against applicant to teach the missing elements, Applicants' claims are non-obvious over Le.

Accordingly, claims 1 – 4, 12 – 16, 19, 21 – 23 and 25 – 33 are patentable over Le, and reconsideration and withdrawal of the rejection is respectfully requested.

***Claim 8 Is Novel Over DeCamp et al***

Claim 8 has been rejected under 35 U.S.C. §103(a) as being obvious over DeCamp. As discussed above, claims 1 – 3 are novel over DeCamp because DeCamp does not teach or suggest a microcatheter system "wherein the flexible cannula is configured to be inserted into a retinal vein and to remain in the retinal vein during infusion and has an outer diameter less than about 100  $\mu$ m and the second cannula is configured to be inserted into the eye." The knowledge in the art does not cure the defects of Decamp. Thus claim 8 is novel over DeCamp. Accordingly, applicants request withdrawal of the rejection and allowance of the claim.

***Claims 8 – 11 and 17 – 18 Are Novel Over Le et al***

Claims 8 – 11 and 17 – 18 have been rejected under 35 U.S.C. §103(a) as being obvious over Le. Applicants respectfully traverse for the reasons set forth above regarding Le.

As Le does not teach or suggest each claim limitation, and it is impermissible for the Examiner to cite Applicants' own disclosure against applicant to teach the missing elements, Applicants' claims are non-obvious over Le.

Accordingly, claims 8 – 11 and 17 – 18 are patentable over Le, and reconsideration and withdrawal of the rejection is respectfully requested.

***Claims 34 and 35 Are Novel Over Le et al In View of Castora et al***

Claims 34 and 35 have been rejected under 35 U.S.C. §103(a) as being obvious over Le in view of Castora (US Pat # 5,947,296). The Examiner asserts that Castora discloses a catheter kit with multiple catheters packaged in one kit and that it would have been obvious to package the catheter of Le as per the organization of Castora. Applicants respectfully traverse the rejection.

As stated above, Le does not disclose, teach or suggest each of Applicants' claim limitations. Castora, like Le, does not disclose, teach or suggest, a flexible cannula configured to be inserted into a retinal vein and to remain in the retinal vein during infusion and has an outer diameter less than about 100  $\mu\text{m}$  and a second cannula configured to be inserted into the eye. Thus, Castora does not cure the deficiencies of Le. Therefore, the present claims are novel over Le in view of Castora. Accordingly, claims 34 and 35 are patentable over Le in view of Castora, and reconsideration and withdrawal of the rejection is respectfully requested.

**CONCLUSION**

It is believed that the application is in condition for immediate allowance, and Applicants respectfully request early favorable action by the Examiner.

Applicants believe that additional fees are not required in connection with the consideration of the within matter. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

M. Humayun, et al.  
U.S.S.N.: 09/754,094  
Page 13 of 13

Should the Examiner wish to discuss any of the amendments and/or remarks made herein,  
the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,



Date: June 3, 2005

---

Stephana E. Patton (Reg. No. 50,373)  
EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, MA 02205  
Telephone: 617-439-4444  
Facsimile: 617-439-4170

Customer No.: 21874